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| APPLICATION NO.              | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-------------|----------------------|---------------------|------------------|
| 10/779,892                   | 02/17/2004  | Kishore Tipirneni    | 51491.0117          | 9636             |
| 20322                        | 7590        | 03/01/2007           | EXAMINER            |                  |
| SNELL & WILMER L.L.P. (Main) |             |                      | BLANCO, JAVIER G    |                  |
| 400 EAST VAN BUREN           |             |                      | ART UNIT            | PAPER NUMBER     |
| ONE ARIZONA CENTER           |             |                      |                     |                  |
| PHOENIX, AZ 85004-2202       |             |                      | 3738                |                  |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 03/01/2007 | PAPER         |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/779,892             | TIPIRNENI, KISHORE  |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Javier G. Blanco       | 3738                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 2/7/2007; 1/11/2007.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 23,24 and 26 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-22 and 25 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 7, 2007 has been entered.

### ***Response to Amendment***

2. Applicant's amendment of claims 1, 3, 5, 6, 9, 1-15, 17, and 22 in the reply filed on January 11, 2007 is acknowledged.

### ***Claim Objections***

3. Claims 9 and 13 are objected to because of the following informalities:

a. Regarding claim 9, please (i) substitute "said second" (see line 3) with --said first--, and (ii) delete "component" (see line 4). Appropriate correction is required.

b. Regarding claim 13, please delete "is" (see line 1). Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 6, 12, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Regarding claim 6, the limitation “said object surface” (see line 2) is indefinite as to the scope of the invention. Claim 1 does not disclose the cap as attached to any object, surface, or portion.
- b. Regarding claim 12, the limitations “said second surface” (see line 2 and line 3), and “said first and second surfaces” (see line 4) lack antecedent basis.
- c. Regarding claim 18, “said bone” (see line 3) lacks antecedent basis.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-6, 8, 11-15, 17, 19-21, and 25 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by HEHL (WO 00/67652 A2).

Referring to Figures 2-4, 6, 8, and 9, Hehl discloses a system including:

- (i) A head component 8 including a tip, cutting threads (see Figures 3 and 4), and fastening threads (as part of the cutting threads);
- (ii) A flexible wire 9 having a first end and a second end, and a first interface including a sawtooth configuration (shown in Figures 4, 6, and 9); and

(iii) A cap 5, said cap having a second interface including an inverse sawtooth configuration (shown in Figures 4, 6, and 9), said cap mates/pairs with said second end of said flexible wire by translating (as in a ratcheting system) along said flexible wire over a surface which restricts reverse translational movement (see Abstract). Cap 5 includes a flat surface, a center hole, and cutting/mating threads 20. Excess wire beyond the cap is removed (inherent in order to avoid exposing nearby/adjacent tissue to excess wire/cable, and clearly shown in Figures 3 and 4). A tool (e.g., driver) is capable of being attached to a portion of the head component. It should be noted that the adjective “flexible” is a broad term. Wire 9 comprises a long, thin shank/body, which will be subject to loads or forces. Said long, thin shank/body will inherently flex to some degree when exposed to said loads or forces.

8. Claims 17, 20, and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fletcher (US 6,050,998 A).

Referring to Figures 1, 2, and 6-10, Fletcher discloses a system including:

- (i) A head component (**first interpretation:** first/distal end of connector portion 26; **second interpretation:** first/distal barbs 28; **third interpretation:** first/distal end of connector portion 26 + first/distal barbs 28)
- (ii) A wire (**first interpretation:** strand 22; **second interpretation:** second/basal end of connector 26; **third interpretation:** strand 22 + second/basal end of connector 26) having a first end and a second end (see column 2, lines 56-65), said wire having a first interface along at least a portion of said wire, wherein said first interface includes a sawtooth configuration (barbs 28); and

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(iii) A cap (connector portion 24) having a second interface component including an inverse sawtooth configuration (internal barbs 28 of connector portion 24) on an inner surface of said cap (see column 3, lines 3-23 and lines 54-56). The excess length of wire beyond the cap is removed (see column 3, lines 23-26). A plate (plate 48) could also be included in the system (Figures 8 and 9; see column 4, lines 7-22). A tool is capable of being attached to a portion of the head component.

***Response to Arguments***

9. Regarding the 102(b) rejection based on Fletcher (US 6,050,998), Applicant's arguments filed January 11, 2007 have been fully considered but they are not persuasive. The Applicant argues that Fletcher '998 does not disclose the head component as "terminating within, said first surface" (see claim 17, line 5). The Examiner respectfully disagrees. As shown in the 102(b) rejection (above), the head component may be interpreted as the first/distal barbs 28. In other words, the first half portion (i.e., distal portion) of barbs 28 may comprise the head component as claimed in claim 17. As shown in Figures 6D and 9, said head component is shown as "terminating within, said first surface".

10. Claims 17-20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Goble et al. (US 5,702,397 A).

Referring to Figures 6, 7, and 9-17, Goble et al. disclose a system including:

- (i) A head component (e.g., anchor 10) including a tip, cutting threads (18), and fastening threads (on the inside surface, or as part of the cutting threads on the outside surface; see column 7, lines 17-28);
- (ii) A flexible wire (sutures 27) having a first end and a second end; and
- (iii) A cap (e.g., plug 30), said cap *configured to mate* with said second end of said flexible wire by translating along said flexible wire over a surface (see, for example, Figure 13) which restricts (e.g., by friction, or by crimping) reverse translational movement. A tool is capable of being attached to a portion of the head component (see Figure 6). The cap includes additional openings (55).

#### ***Response to Arguments***

11. Regarding the 102(b) rejection based on Goble et al. (US 5,702,397 A), Applicant's arguments filed January 11, 2007 have been fully considered but they are not persuasive. The Applicant argues that Goble et al. '397 does not disclose the head component as "affixed to the flexible wire" (see claim 17, line 3) prior to insertion into the bone. The Examiner respectfully disagrees. The claim language does not require the attachment to occur "prior to insertion into the bone". Also, the cap does translate along the wire (e.g., sutures). Further, a middle portion of the wire (e.g., sutures) "crosses an interface between said first and second surface" since that first and second surfaces could be located one next to the other.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dakin et al. (US 6,368,326 B1; cited in Applicant's IDS) in view of Cachia (US 5,893,850 A; cited in Applicant's IDS).

Referring to Figures 1-5, Dakin et al. disclose a system including:

(i) A head component (e.g., fastener 20) including a tip, cutting threads (20.4), and fastening threads (on the inside surface, or as part of the cutting threads on the outside surface);  
(ii) A flexible wire (cord 22) having a first end and a second end; and  
(iii) A cap (**first interpretation:** fastener 24, which has cutting threads 24.2, bore 24.3, and interior threads 24.4; **second interpretation:** locking device/screw 28, which has threads 28.1; **third interpretation:** fastener 24 + locking device/screw 28), said cap mates/pairs with said second end of said flexible wire by translating along said flexible wire over a surface which restricts (e.g., by friction, or by crimping) reverse translational movement. Fastener 24 comprises a substantially flat end, a center hole 24.3, and additional openings 24.5, which additional openings are capable of expansion. Excess wire beyond the cap is removed (inherent in order to avoid exposing nearby/adjacent tissue to excess wire/cable, and clearly shown in Figures 13). A tool (e.g., driver) is capable of being attached to a portion of the head component (see entire document, particularly column 7, lines 8-14). A tensioner is used for applying tension to said

wire (see, for example, Figure 1). A surgical plate is configured to mate with a surface of bone (see Figures).

The cap mates/pairs with the second end of the flexible wire. The excess length of the second end of the flexible wire will be removed (inherent in order to avoid exposing nearby/adjacent tissue to excess wire/cable, and clearly shown in Figures 13), but the cap will engage the remaining portion of the second end of the flexible wire. Notice in Figure 1 how a middle wire portion extends across an interface between a first bone portion 18 and a second bone portion 16. Notice in Figure 13 how a first end of the flexible wire is attached/mated/paired with the head component, and the second end of the flexible wire is attached/mated/paired with the cap.

Dakin et al. disclose the invention as claimed except for particularly disclosing the cap as comprising an inverse sawtooth configuration on an inner surface (e.g., bore) for translating along the flexible wire. However, this is already known in the art. For example, Cachia discloses a system comprising a cap/wire connection wherein the wire comprises a sawtooth configuration (retention structure 44) along at least a portion of said wire, and the cap comprises an inverse sawtooth configuration (retention structure 42) on an inner surface of said cap (see column 4, lines 23-32 and lines 50-67), wherein the cap translates along said wire in order to provide resistance to movement of the cap in the proximal direction relative to the wire (see column 4, lines 23-32 and lines 50-67). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a system comprising a cap/wire connection wherein the wire comprises a sawtooth configuration along at least a portion of said wire, and the cap comprises an inverse sawtooth configuration on an inner

surface of said cap, wherein the cap translates along said wire, as taught by Cachia, with the system of Dakin et al., in order to provide resistance to movement of the cap in the proximal direction relative to the wire.

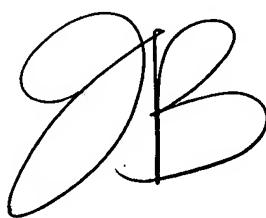
*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco

February 26, 2007



David H. Willse  
Primary Examiner